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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,198	03/01/2002	Daryl Real	5407/1J328-US1	8576
7590 11/30/2005				
DARBY & DARBY P.C. 805 Third Avenue New York, NY 10022		EXAMINER JAGOE, DONNA A		
		ART UNIT PAPER NUMBER		
		1614		

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,198	REAL ET AL	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2005 and 06 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 31 January 2005 has been entered.

Previous Rejections

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Musser et al.¹, Trottier et al.², J. Arthington³ Samland et al. 1999(CB).

The claims are drawn to a method of enhancing the reproductive performance of a sow which comprises feeding to a sow during at least two gestation periods and optionally during lactation, breeding and/or prebreeding, amounts of L-carnitine or a salt thereof and a trivalent chromium salt sufficient to enhance the reproductive performance of said sow. Dependent claims are drawn to the amounts of L-carnitine and trivalent chromium salts in mg/day or ug/day and a method of feeding sow diet supplemented with L-carnitine and trivalent chromium salts.

¹ Effects of L-Carnitine on Performance of Gestating and Lactating Sows, Swine Day 1999 (IDS from 6/20/03 document #2).

² Effect of Supplemental Chromium Tripicolinate on Sow Productivity and Blood Metabolites, 1998 (IDS from 12/18/2002, document #9).

³ Millennium Technologies The Original L-Carnitine/Chromium Picolinate Supplement, How and Why it Works? 4/27/00, (IDS from 5/8/02, document #10)

Musser et al. teach L-carnitine added in an amount of 50 ppm to sow diet to assess gestation and lactation and litter performance. L-carnitine increased litter birth and weaning weights (see abstract). After weaning, sows were monitored once daily for estrus. Subsequent farrowing rate, total number of pigs born and number born alive were also determined. Table 5 demonstrates the effects of L-carnitine on subsequent reproductive performance where the number of total born pigs increased and the number of pigs born alive increased.

It does not teach the addition of trivalent chromium salts.

Trottier et al. teach chromium tripicolinate to sow diets to increase sow productivity through increasing litter size. 200 ppm of chromium tripicolinate fed to sows increase litter size and reduced wean to estrus interval, thus enhancing sow reproductive performance (see summary). Sows remained on the study for *three consecutive farrowings* (page B-2, paragraph 2). There is a noted improvement in litter size in cycle 2 with continuous chromium supplementation at 200 ppm (page B-3, paragraph 4).

It does not teach the addition of L-carnitine.

Samland et al. teach the addition of L-carnitine and chromium nicotinate (a trivalent salt) in the amount of 200 ppm of each to a sow diet (page 33, column 1, paragraph 2). Samland et al. teach that L-carnitine and chromium nicotinate are two regulatory nutrients that influence insulin signaling. Increased insulin secretion has been shown to increase maturation of ovarian follicles and ovulation rate (see abstract). The claims differ in that the combination of L-carnitine and chromium nicotinate is fed to

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gilts, and not through at least two gestation periods. However, it would have been obvious to supplement animal feed with chromium and L-carnitine motivated by the teaching of Musser et al and Trottier et al. above who teach that individually, L-carnitine and trivalent chromium are beneficial to sow reproductive performance beyond the first parity. It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. *In re Kerkhoven* 205 USPQ 1069. The idea for combining said compositions flows logically from their having been individually taught in the prior art. *In re Crockett* 126 USPQ 186, 188.

The fact that a first component is in no way related to the second component, but where each has the same utility, does not detract from the obviousness of combining them. *In re Linder*, 457 F.2d 506, 507 (CCPA 1972). (Holding that it would have been obvious to combine two known dispersants, since one skilled in the art would have expected a mixture of such dispersants to also be a dispersant). Moreover, picking and choosing known components from several references, each which itself discloses a plurality of such components, is permissible where each component has the same individual utility. *In re Dial*, 326 F.2d 430 (CCPA 1964). (Holding that it would have been obvious to have combined four individual stabilizers for halogenated hydrocarbon solutions from three different references, where there was no evidence in the record establishing that Applicant's claimed combination of stabilizers was any more effective or in any way otherwise different in inhibiting the decomposition of halogenated hydrocarbons than any single member of that combination. *Id.* at 432.)

See also *In re Shannon* 148 USPQ 504 (one step laminate is obvious from two step laminate).

Regarding applicants suggestion that these results are unexpected because of the synergy of the two agents, J. Arthington is cited to provide motivation to employ L-carnitine and chromium picolinate to work synergistically since Arthington teaches that L-carnitine and chromium picolinate work synergistically when fed together to reduce the amount of fat deposition during the protein phase of growth. It does not teach enhancing reproductive performance, however, Arthington teaches that chromium is necessary for optimal insulin function and glucose uptake in cells and L-carnitine aids fatty acid metabolism. Samland et al. (above) teaches that increased insulin secretion has been shown to increase maturation of ovarian follicles and ovulation rate (see abstract). Thus, it would have been obvious to employ synergistic combination of L-carnitine and trivalent chromium to enhance reproductive performance motivated by the teaching of Samland et al. that the synergistic combination of Arthington would increase maturation of ovarian follicles and ovulation rate.

Response to Arguments

Applicant has amended claims 1 and 4 to recite farrowing rate instead of reproductive performance. Farrowing rate is defined as the number of sows farrowed divided by the number of sows bred in the same batch expressed in percent. To farrow is to produce a litter of pigs. Studying the rejection above, Musser et al. teach in Table 5 the effects of L-carnitine on subsequent reproductive performance where the number

of total born pigs increased and the number of pigs born alive increased. It teaches L-carnitine and not trivalent chromium salts.

Trottier et al. teach that the addition of trivalent chromium salts to sow diets increase sow productivity through increasing litter size. It does not teach the L-carnitine.

Samland et al. teach L-carnitine and chromium nicotinate (a trivalent salt of chromium) 200 ppm of each in sow diet. It differs in that the combination is fed to gilts (A young sow that has not farrowed), and not through at least two gestation periods. However, Samland et al. teach that L-carnitine and chromium nicotinate are two regulatory nutrients that influence insulin signaling. Increased insulin secretion has been shown to increase maturation of ovarian follicles and ovulation rate. To increase the ovulation rate would increase the farrowing rate since a greater ovulation rate would lead to an increased number of sows farrowed divided by the number of sows bred in the same batch expressed in percent. Regarding new claims 16 and 17, the claims are rejected on the same grounds as the current grounds of rejection for the reasons indicated in the stated grounds of rejection.

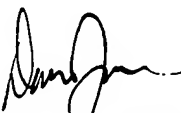
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Donna Jagoe
Patent Examiner
Art Unit 1614

11/28/2005



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